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**REMARKS**

Applicants respectfully request the Examiner to reconsider the present application in view of the foregoing amendments to the claims.

Previously, claims 1-4, 6-11, 13-18, 20-23, 25-26, 28-30 and 33-42 were pending in this application. Herein, claim 43 has been added and claims 37-38 have been amended. Thus, claims 1-4, 6-11, 13-18, 20-23, 25-26, 28-30 and 33-43 are pending in the present application.

No new matter has been added by way of this new claim since it is supported throughout the present specification, including page 4, line 13, page 7, lines 11-17 and the various Examples. New claim 43 excludes certain amounts of materials, such as wax, when that added material would affect the basic and novel properties of the claimed invention. The changes to claims 37-38 are editorial in nature (see page 3 of the specification).

Based upon the above considerations, entry of the present amendment is respectfully requested.

In view of the following remarks, Applicants respectfully request that the Examiner withdraw all rejections and allow the currently pending claims.

**Issues Under 35 U.S.C. § 102(b)**

Claims 1-3, 6-10, 13-17, 20-22, 25, 28-30, 39 and 41-42 stand rejected under 35 U.S.C. § 102(b) as anticipated by Aoki '850 (Aoki et

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al.; JP Publication Number 07267850 A). Also, claims 1-3, 7-10, 13-17 and 21 stand rejected under 35 U.S.C. § 102(b) as anticipated by the drug information on Vantin®, by Pharmacia & Upjohn (obtained through on-line PDR). Applicants respectfully traverse since each reference fails to disclose all features as instantly claimed, and reconsideration and withdrawal of these rejections are respectfully requested.

Distinctions over Aoki '850

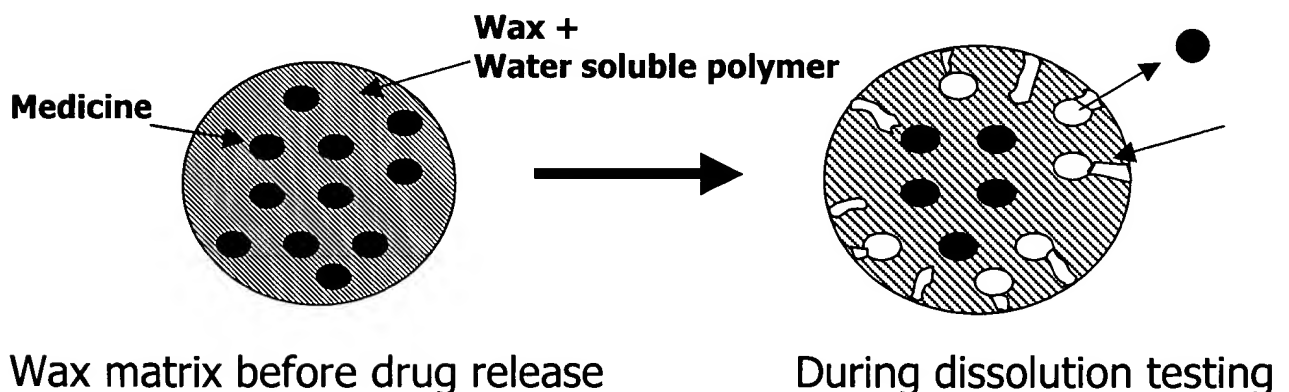
The Examiner refers Applicants to various parts of the cited Aoki '850 reference. However, Applicants respectfully submit that the Aoki '850 composition is different from the present invention, wherein Aoki '850 fails to disclose the interaction of the basic medicine with an acidic polysaccharide as instantly claimed (see independent claims 1, 8, 22, 25, 28-30 and 41). There is no disclosure in JP '850 of the intimate contact of the claimed ingredients, nor is there any recognition of the electrical interaction that can prevent the unpleasant taste of a basic medicine. Instead, the wax-like matter of JP '850 is the essential ingredient, which also prevents any intimate contact between the ingredients and/or electrical interaction. Specifically, in JP '850, the wax is used to encapsulate the unpleasant tasting medicine and the wax repels water (i.e., interaction with saliva), and is not the same as decreasing the interaction between the

medicine itself and the tongue when the composition is in the user's mouth.

In fact, Applicants respectfully submit that the incorporated wax in Aoki '850 prevents an electric interaction between its basic medicine and disclosed "cellulose system macromolecules" (see paragraphs [0009] and [0011] for the described ingredients of Aoki '850). Aoki '850 uses a combination of medicine + water-soluble polymer + wax. When the Aoki '850 preparation is orally administered to a person, the moisture (or water) in the saliva does not penetrate the tablet, or at the very least the penetrating speed is very slow. With the Aoki '850 preparation, the water-soluble polymer component (see the figure below) dissolves gradually in the gastro-intestinal tract, and not in the mouth. The dissolved water-soluble polymer makes water in the channel shown below:

**Aoki, Shigeru et al.**

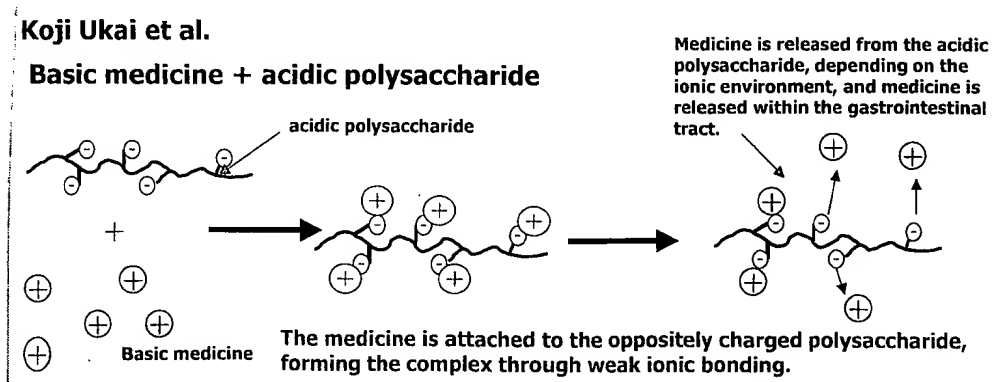
**Medicine + Wax + Water soluble**



As a result, the medicinal part dissolves and gradually travels through the water channel in the gastro-intestinal tract since the wax repels water. Therefore, the wax component prevents water from penetrating the medicinal preparation, such as a tablet. Accordingly, water (or moisture) does not penetrate the Aoki '850 preparation, even if the medicine component and water-soluble polymer exists together in the preparation. Therefore, an electric interaction is not produced in the Aoki '850 composition. Thus, Applicants respectfully submit that Aoki '850 fails to disclose all features as instantly claimed.

Also, the current Office Action has not sufficiently countered Applicants' position regarding this claimed feature (see Applicants' reply of November 25, 2003, page 18+). Applicants respectfully request the Examiner to acknowledge that Aoki '850 fails to disclose this feature.

With the present invention, on the other hand, the moisture (or water) in the saliva penetrates the tablet rapidly. This leads to the electric interaction, as claimed, between the basic medicine and acidic polysaccharide in the tablet. Such electric interaction is shown below:



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So upon oral administration, the electric interaction is produced which masks the bitter taste of the basic medicine.

Therefore, Applicants respectfully maintain their position that Aoki '850 fails to disclose all features as instantly claimed and that this rejection has been overcome. Because "a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference," the cited Aoki '850 reference cannot be a basis for a rejection under § 102(b). See *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Withdrawal of this rejection is respectfully requested.

Internet Article Improperly Cited and Distinctions Over Internet Article

With regard to the cited the Internet article of drug information on Vantin®, Applicants respectfully submit that the Vantin® article is improperly cited against the claimed invention. This article was obtained on-line (on the Physicians' Desk Reference website), and there is no date preceding the priority date of this application (see the Examiner's PTO-892 form submitted with the Office Action of March 27, 2002 showing a revision date of the year 2000). Thus, Vantin® is not considered a prior art reference. See M.P.E.P. § 2128 ("Date of Availability" section, where no publication date of an Internet articles

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means the article cannot be relied upon as prior art). In addition, there is no proof that this article represents the state of the art when the present invention was made.

Assuming *arguendo* that the reference was publicly available prior to the filing date of the present application, the cited reference fails to disclose all features as instantly claimed (i.e., electric interaction). Under *Verdegaal Bros.*, Applicants submit that this rejection has been overcome. Thus, Applicants respectfully submit that this rejection is improper and/or has been overcome. Withdrawal of this rejection is respectfully requested.

***Issues Under 35 U.S.C. § 103(a)***

Claims 4, 11, 18, 23, 26, 29-30, 33-38 and 40 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Aoki '850 in view of Matoba et al. '612 (U.S. Patent No. 5,464,612). Applicants respectfully traverse, and reconsideration and withdrawal of this rejection are respectfully requested.

The Examiner states that Matoba '612 is used as supportive evidence to show that basic medicines have known bitter taste (see the Office Action at page 5, lines 13-15 and the sentence bridging pages 5-6). However, Applicants respectfully submit that the Examiner still has not accounted for how Matoba '612 can be properly combined with the primary reference of Aoki '850, which is required. Though any two references could

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be theoretically combined, a *prima facie* case of obviousness requires a certain amount of motivation and reasonable expectation of success which Applicants submit has not been found. In summary, Applicants respectfully submit that one of ordinary skill in the art would not be motivated or reasonably expect to be successful in combining Aoki '850 with Matoba '612, and that not even all claimed features are disclosed in such a proposed combination.

#### Lack of Disclosure of All Claimed Features

First, Applicants respectfully submit that neither of the cited references discloses the electric interaction feature as instantly claimed. Each reference does not account for the deficiencies of each other, and one of ordinary skill in the art cannot account for these deficiencies either upon a reading of these references. In this regard, Applicants also request consideration of the above comments as to how the Aoki '850 wax preparation that is orally administered to a person leads to little or no penetration of the medicine, and how there is no electric interaction or intimate contact in Aoki '850 as instantly claimed. Thus, Applicants respectfully submit that the instant rejection is improper for the additional reason in that a *prima facie* case of obviousness requires disclosure of all claimed features. See *In re Vaeck*, 947 F.2d, 488, 493, 20 U.S.P.Q.2d 1438, 1442 (Fed. Cir. 1991); see also *In re Kotzab*, 55 U.S.P.Q.2d 1313, 1316-17 (Fed. Cir. 2000).

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The Other Requirements for a *Prima Facie* Case of Obviousness Are Not Satisfied

Second, the cited secondary reference of Matoba '612 describes a coating composition, whereas Aoki '850 requires the wax fusion of ingredients. This is an inconsistent feature between the references such that the skilled artisan would not know how to achieve the present invention.

Applicants submit that there are three possible sources of motivation to combine references: the nature of the problem to be solved, the teaching of the prior art, and the knowledge of persons of ordinary skill in the art. *In re Rouffet*, 149 F.3d 1350, 1357, 47 USPQ2d 1453, 1457-58 (Fed. Cir. 1998). Here, Matoba '612 solves problems in the art by using a clad powdery and granular preparation of medically active ingredients and ion exchangers (see Abstract; see also claim 1 at Col. 20). The disclosed coating composition includes a list of water-soluble polymers, water-insoluble polymers, acid-soluble polymers, and enteric polymers (see Col. 6, lines 18-25). However, Aoki '850 uses wax infusion, which is technologically different from Matoba '612. One of ordinary skill in the art would not be motivated in combining these references in order to achieve the present invention.

Further, the present invention does not use wax as required by the Aoki '850 reference (which also leads to a different mechanism of action



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of the composition when ingested by the user). Wax, melting points and the fusing of the wax with other ingredients by heat is discussed throughout Aoki '850 (see Claim 11; lines 1 and 6 of paragraph [0010]; line 1 of paragraph [0011]; line 4 of paragraph [0013]; line 3 of paragraph [0014]; the Examples; etc.). Thus, Applicants respectfully submit that the skilled artisan would not even refer to the Aoki '850 reference in the first place in order to achieve the present invention.

There is also no reasonable expectation of success when one of ordinary skill in the art would have to take away either the granular preparation of Matoba '612, or take away the wax infusion of Aoki '850 so as to achieve the present invention. Under *Vaack*, Applicants respectfully submit that the requirements for a *prima facie* case of obviousness have not been satisfied.

Overall, Applicants respectfully submit that a *prima facie* case of obviousness has not been established. Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

#### Inoperability of the References as Proposed in the Office Action

Applicants also submit that this rejection is improper and has been overcome because combining the references as asserted by the Examiner would render the cited references inoperable.

As the Federal Circuit has recent held: "If references taken in combination would produce a 'seemingly inoperative device,' we have held

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that such references teach away from the combination and thus cannot serve as predicates for a prima facie case of obviousness." See *McGinley V. Franklin Sports Inc.*, 60 USPQ2d 1001, 1010 (CAFC 2001) (citing *In re Sponnoble*, 405 F.2d 578, 587, 160 USPQ 237, 244 (CCPA 1969) (references teach away from combination if combination produces seemingly inoperative device) and *In re Gordon*, 733 F.2d 900, 902, 221 USPQ 1125, 1127 (Fed. Cir. 1984) (inoperable modification teaches away)). Here, one having ordinary skill in the art would have to delete the wax that is required by Aoki '850 in order to achieve the present invention. Or, the skilled artisan would have to subtract the coated composition of Matoba '612 in order to achieve the present invention as suggested by the Examiner. Thus, the proposal in the Office Action renders each of the cited references into an inoperable product.

Applicants add that the claimed combination cannot change the principle of operation of the primary reference or render the reference inoperable for its intended purpose. See M.P.E.P. §§ 2143.01, 2145(III). That is the case here. Thus, Applicants respectfully submit that the instant rejection is improper and request that it is withdrawn.

#### Lack of "Clear and Particular" Guidance

While the reference need not expressly teach that the disclosure contained therein should be combined with another, see *Motorola, Inc. v. Interdigital Tech. Corp.*, 43 USPQ2d 1481, 1489 (Fed. Cir. 1997), the

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showing of combining references "must be clear and particular". See *In re Dembiczak*, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999). Here, there is no guidance in any of the cited references of Aoki '850 and Matoba '612 to achieve the formulations as presently claimed. Further, the mere fact that disclosures can be combined does not make the combination obvious unless the art also contains something to suggest the desirability of the combination. See, *In re Gordon*, 221 USPQ 1125, 1127) and *In re Imperato*, 179 U.S.P.Q. 730, 732 (CCPA 1973). Matoba '612 does not describe or recognize using the wax of Aoki '850, and Aoki '850 does not disclose or recognize using the clad powdery preparation of Matoba '612. Thus, the instant rejection is improper under *Dembiczak* and/or *Gordon*.

Request for Evidence Supporting Rejection and Sang Su Lee

If the Examiner continues to maintain that it is a "logical extension of the combined references to have include donepezil hydrochloride ... to prevent their unpleasant taste" (see the Office Action at page 4, third paragraph), Applicants hereby challenge this assertion and request that the Examiner produce evidence to support this assertion regarding the logical extension. Alternatively, if the Examiner is relying upon personal knowledge to support the finding of what is known in the art, the Examiner is respectfully requested to provide an affidavit or declaration setting forth specific factual statements and explanations to support such an assertion. In this regard the Examiner is referred

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to 37 C.F.R. § 1.104(d)(2). With regard to motivation or suggestion to select the instantly claimed invention, Applicants note that any conclusory statements of similarity or motivation, without any articulated rationale or evidentiary support, do not constitute sufficient factual findings. See M.P.E.P. § 2144.08(III).

Further, Applicants respectfully submit that the Examiner's reasons for combining Aoki '850 with Matoba '612 is contrary to the ruling in *In re Sang Su Lee*, 61 USPQ2d 1430 (Fed. Cir. 2002), wherein the Federal Circuit held that the Board of Appeals could not merely rely on what is "common-knowledge and common sense" in the art to sustain a rejection under 35 U.S.C. § 103. Instead, a determination of patentability must be based on factual evidence. Further, no proper motivation has been shown in the Office Action because the U.S.P.T.O. has failed to identify the specific principle known to one of ordinary skill in the art that suggests the claimed method. *Sang Su Lee*, 61 U.S.P.Q.2d at 1434 (the Board must identify specifically the principles, known to one of ordinary skill, that suggest the claimed combination) (citing *In re Rouffet*, 47 U.S.P.Q.2d 1453, 1459 (Fed. Cir. 1998)). Applicants respectfully submit that the instant rejection is improper since no specific principle as been set forth and request withdrawal thereof.

An Impermissible Level of Hindsight Reconstruction Has Been Applied

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The Office Action states that Aoki '850 could be combined with Matoba '612 because it is a logical extension to include donepzail hydrochloride (see the Office Action at page 4, third paragraph). Applicants respectfully traverse this conclusion.

Most inventions are after their presentation easy to understand as well as the benefit of the invention. Therefore, it is normally easy to search in the literature for pieces of information and to put them together in a manner not suggested and to overlook under which circumstances the pieces of information were disclosed. However, it is not sufficient to be able to show that certain pieces of information could have been combined by a person skilled in the art as suggested in the Office Action and circumstances that speak against a combination have to be considered. The essential question is if one having ordinary skill in the art, and with no knowledge of the actual invention, would have found it obvious, guided by the disclosure in the references (if the references are properly referred to in the first place), to combine them in such a manner that all the necessary characteristics of the invention were revealed. If the references do not disclose all the necessary characteristics then no proper combination can be made. Here, Applicants submit that not even the electric interaction is disclosed. Further, the references are technologically inconsistent. Thus, Applicants respectfully submit that an impermissible level of hindsight reconstruction has been applied for forming the instant rejection.

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Though Applicants recognize some hindsight is allowable, Applicants submit that an impermissible level has been applied in the instant situation ("It is wrong to use the patent in suit as a guide through the maze of prior art references, combining the right references in the right way so as to achieve the result of the claims in suit." *Orthopedic Equip. Co., Inc. et al. v. United States*, 217 U.S.P.Q. 193, 199 (Fed. Cir. 1983)). Reconsideration and withdrawal of this rejection are respectfully requested.

#### **Errors**

The Examiner, at page 2 of the Office Action states that there exists numerous typographical errors in the claims (i.e., medicinal substances). Clarification is requested of which ingredients are misspelled.

#### **Request for Copy of PTO-1449 Form**

Applicants respectfully request a copy of the PTO-1449 form, that was submitted with the Information Disclosure Statement of March 13, 2003, having the Examiner's initials next to each cited reference.

#### **Conclusion**

A full and complete response has been made to all issues as cited in the Office Action. Applicants have taken substantial steps in

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efforts to advance prosecution of the present application. Thus, Applicants respectfully request that a timely Notice of Allowance issue for the present case.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Eugene T. Perez (Reg. No. 48,501) at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

Pursuant to 37 C.F.R. §§ 1.17 and 1.136(a), Applicant(s) respectfully petition(s) for a three (3) month extension of time for filing a reply in connection with the present application, and the required fee of \$950.00 is attached hereto.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

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